

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOARD OF REGENTS, THE UNIVERSITY
OF TEXAS SYSTEM and TISSUEGEN, Inc.

Plaintiffs,

v.

BOSTON SCIENTIFIC Corp.

Defendant.

Civil Action No. 18-392-GBW

MEMORANDUM ORDER

Plaintiffs Board of Regents, The University of Texas System’s (“UTBOR”) and TissueGen, Inc.’s (“TissueGen”) (collectively, “Plaintiffs”) First Amended Complaint alleges that Defendant Boston Scientific Corp. (“BSC”) directly, indirectly, and willfully infringed, via its “Synergy” brand coronary stents (the “Accused Products”), U.S. Patent No. 6,596,296 (“the ’296 patent”). D.I. 124 ¶¶ 1–3, 79, 89, 93–94. On January 3, 2023, the parties submitted proposed final jury instructions for Phase 2 of this bifurcated trial that contained numerous disputes. *See* D.I. 272. During the final pretrial conference on January 12, 2023, the Court provided to the parties a draft final jury instruction as to patent marking entitled “4.7 DAMAGES—Date of Commencement of Damages” and ordered the parties to submit joint letter briefing “that provides the parties’ feedback on the Court’s proposed Phase [2] Final Jury Instruction 4.7 as to the [patent] marking issue[.]” D.I. 276 ¶ 10. For the reasons below, the Court adopts-in-part and rejects-in-part the parties’ proposed edits to its jury instruction. *See* D.I. 285. The Court writes solely for the benefit of the parties.

UTBOR and TissueGen ask the Court to make three sets of changes to the Court’s proposed instructions. First, UTBOR and TissueGen argue that “the Court’s proposal conflates the

obligations of the patentee (UT[BOR]) and the exclusive licensee (TissueGen) with respect to marking. The patentee, however, is the party responsible for complying with marking.” D.I. 285 at 1. UTBOR and TissueGen propose to replace “TissueGen may prove that it gave notice” with the passive voice statement that “you may find notice to the public in general was given” and to delete “but not TissueGen” from the instruction “you may find that [UTBOR], but not TissueGen, complied with the ‘marking’ requirement if [UTBOR] can prove by a preponderance of the evidence that it made reasonable efforts to ensure compliance with the marking requirements by its licensees, including by TissueGen.” The Court rejects UTBOR’s and TissueGen’s proposed alterations. Section 287(a) of the Patent Act applies the marking requirement to “[p]atentees, and persons making, offering for sale, or selling within the United States any patented article for or under them” 35 U.S.C. § 287(a). For that reason, “[a] patentee’s licensees must also comply with § 287.” *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 950 F.3d 860, 864 (Fed. Cir. 2020) (“*Arctic Cat I*”). UTBOR’s and TissueGen’s proposal does not clarify which party bears the burden to mark and may leave jurors confused as to whether BSC has a marking obligation, which it does not. Further, TissueGen—as a licensee—may not raise a “reasonable efforts” defense. *See Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017) (“*Arctic Cat F*”) (applying the “rule of reason” inquiry to the patentee only).

Second, the Court proposed to instruct the jury, as to actual notice, that

[a] second way [UTBOR] and TissueGen can prove that they gave notice of the ’296 patent is to prove that they directly notified Boston Scientific with a specific claim that the Synergy stents infringed the ’296 patent. However, Boston Scientific’s knowledge of a specific infringing device is not a legal prerequisite to such a finding.

UTBOR and TissueGen propose to change “Boston Scientific’s knowledge” to “UTBOR and TissueGen’s knowledge” and to add the following sentence: “In other words, you are permitted to

find actual notice prior to the date UTBOR and TissueGen discovered Boston Scientific's infringement." D.I. 285 at 2. UTBOR and TissueGen argue that "a patentee does not need to identify a specific allegedly infringing product or device and actual notice may still be given prior to the date that a patentee has knowledge of a specific infringing device." D.I. 285 at 1. BSC argues that the case from which the "knowledge of a specific infringing device" instruction came, *Minks v. Polaris Indus., Inc.*, 546 F.3d 1364 (Fed. Cir. 2008), is distinguishable because the instruction was specific to the relationship between the parties to that case. D.I. 285 at 4. Moreover, BSC argues that an allegation of infringement by a specific product is required. *Id.*

The Federal Circuit has explained that

[plaintiff/patentee] argues that [its] proposed instruction [(unlike the instruction that the Court gave)] indicates that a patentee can provide sufficiently specific notice to an accused infringer before the patentee discovers the actual infringement by the accused. We agree with [plaintiff/patentee] that the given instruction [from the district court] does not fairly and correctly state the issues and the law; the jury should have been more clearly instructed that it was permitted to find notice prior to the date [plaintiff/patentee] discovered [defendant's] infringement.

Minks, 546 F.3d at 1376. The Federal Circuit went on to explain that "knowledge of a specific infringing device is not a legal prerequisite" to a finding of actual notice. *Id.* at 1377. More recently, however, the Federal Circuit explained that "[a]ctual notice requires the affirmative communication of a specific charge of infringement by a specific accused product or device." *Arctic Cat II*, 950 F.3d at 864 (citation omitted).

The Court accepts BSC's proposal to delete the instruction that "knowledge of a specific infringing device is not a legal prerequisite" because the Court has not been able to find—and the parties do not provide—a Federal Circuit case that repeats the instruction from *Minks*. Rather, the caselaw suggests that, outside an "ongoing" relationship, as in *Minks*, 546 F.3d at 1377, actual notice must specify a specific infringing product. The Court also finds that UTBOR's and

TissueGen’s proposed additional sentence is too broad, since the Federal Circuit requires a specific charge of infringement by a specific product, and Plaintiffs’ proposed instruction could confuse the jury as to the need for such specificity.

Third, UTBOR and TissueGen propose to modify the final paragraph of the Court’s proposed instruction to state that the jury must determine whether “UTBOR complied with the marking requirements” rather than determining whether “they [i.e., UTBOR and TissueGen] complied with the marking requirements.” D.I. 285 at 2. However, “[a] patentee’s licensees must also comply with § 287.” *Arctic Cat II*, 950 F.3d at 864. Thus, the Court rejects this proposal.

BSC raises five sets of objections to the Court’s proposed patent marking instruction. First, BSC objects to and recommends deletion of the following sentence in the proposed jury instruction: “You should only consider [the marking requirement for] products that were shown or sold to third parties with whom there was no confidential agreement.” D.I. 285 at 2. BSC argues that § 287(a) includes “no exception . . . for ‘confidential’ sales, nor any requirement that the products required to be marked even be distributed” and “applies equally to those simply ‘making’ patented articles as well as those selling them.” *Id.* The marking statute requires “[p]atentees, and persons making, offering for sale, or selling within the United States any patented article for or under them” to mark their products. 35 U.S.C. § 287(a). The Court initially proposed to add an exemption for confidential sales at Plaintiffs’ urging.¹ In *Corelogic Information Solutions v.*

¹ The purposes of the marking statute are “(1) helping to avoid innocent infringement; (2) encouraging patentees to give public notice that the article is patented; and (3) aiding the public to identify whether an article is patented.” *Arctic Cat I*, 876 F3d at 1366. In its initial proposal, the Court reasoned that a confidential sale would not lull unsuspecting third-parties into a belief that no patent applied to infringing products. However, upon reconsideration, even confidential sales create risk of innocent infringement, and the plain text of § 287(a) offers no confidential sale exception. If, for example, the recipient of a confidential sale that was unaware of the patent then sold its own product that infringed, innocent members of the public could be led to believe that the invention was unpatented. The Court does not decide here whether a narrower instruction, such

Fiserv, the one case Plaintiffs cited in support of their proposal, D.I. 272 at 26 n.44, the district court sided with plaintiff at summary judgment because plaintiff argued, in part, that its only unmarked product was held internally and never released to third parties, 2012 WL 4635994, at *2 (E.D. Tex. Sept. 29, 2012). Here, by comparison, Plaintiffs admit that TissueGen provided unmarked products “to a licensee on the patent under a[] [non-disclosure agreement]” in “private transactions pursuant to consulting agreements” D.I. 288 at 73:20–74:11. Plaintiffs have failed to cite any case that would exempt from the plain text of the marking statute a sale made confidentially. Thus, the Court accepts BSC’s proposed deletion.

The Court considers BSC’s third argument before its second argument. The Court proposed to instruct the jury that “you may find that [UTBOR], but not TissueGen, complied with the ‘marking’ requirement if [UTBOR] can prove by a preponderance of the evidence that it made reasonable efforts to ensure compliance with the marking requirements by its licensees, including by TissueGen.” BSC argues that “the ‘reasonable efforts’ doctrine only applies to marking by third parties unrelated to the patentee and is legally inapplicable in this case.” D.I. 285 at 3. BSC argues that UTBOR’s ten percent ownership stake in TissueGen means that the parties are *not* “unrelated.” *Id.* In 1996, the Federal Circuit applied the so-called “rule of reason” analysis to “third parties unrelated to the patentee[.]” *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996). However, in 2010, the Federal Circuit explained that the “rule of reason” analysis applied “when others than the patentee are involved in sales to the public[.]” *Funai Elec. Co. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1375 (Fed. Cir. 2010). Here, BSC admits that UTBOR and

as one that exempted from the marking requirement only transactions with patent licensees, would be proper, since Plaintiffs never requested one. Instead, Plaintiffs proposed a much broader instruction: “[a] patented article that never enters the public domain does not create a duty to mark the product.” D.I. 272 at 25. *But see* D.I. 288 at 73:25–74:2 (“I don’t think as a matter of law that you have to mark something that you provide to a licensee on the patent under an NDA.”).

TissueGen are separate organizations and provides no reason for the Court to reject the corporate distinctions between them. The jury may reasonably consider evidence about the closeness of the relationship between UTBOR and TissueGen when it evaluates whether UTBOR's efforts as to marking were "reasonable" in this case. Thus, the Court rejects BSC's proposed deletion of the "reasonable efforts" instruction.

Next, BSC argues that "there is no need to provide extensive background instruction related to the determination of whether a product made or sold by TissueGen has been sufficiently 'marked'—Plaintiffs do not contend in this case that any fiber products made by TissueGen were marked." D.I. 285 at 3 (emphasis omitted). Indeed, Dr. Kevin Nelson of TissueGen admits that TissueGen never marked any products with the '296 patent. D.I. 263-20, Ex. 3 at 65. However, as a practical matter, the Court must instruct the jury on what constitutes "marking" so that the jury can evaluate UTBOR's "reasonable efforts" to ensure TissueGen's compliance with the marking requirement. Thus, the Court rejects BSC's proposed deletion.

Fourth, BSC objects to the Court's instruction that "[UTBOR] and TissueGen must prove by a preponderance of the evidence that Boston Scientific knew of the '296 patent and of the alleged infringement by the Synergy stents." D.I. 285 at 4. According to the Federal Circuit,

the actual notice requirement of § 287(a) is satisfied when the recipient is informed of the identity of the patent and the activity that is believed to be an infringement, accompanied by a proposal to abate the infringement, whether by license or otherwise. It is irrelevant under § 287 whether the defendant knew of the patent or knew of his own infringement. The correct approach to determining notice under § 287 must focus on the action of the patentee, not the knowledge or understanding of the infringer.

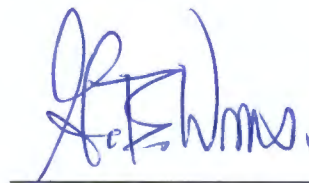
Lubby Holdings LLC v. Chung, 11 F.4th 1355, 1360 (Fed. Cir. 2021) (cleaned up). Thus, the Court shall modify its instruction to read as follows: "UTBOR and TissueGen must prove by a

preponderance of the evidence that **they informed** Boston Scientific of the **identity of the '296** patent and of the alleged infringement by the Synergy stents.” (bolded text added).

Fifth, BSC “objects to any reference to the damages period beginning on November 20, 2011, as Plaintiffs’ damages expert states that ‘the Damages Period would begin on the date of first infringement, October 2015 . . . [.]’ D.I. 285 at 4. However, if the jury finds that TissueGen’s products did not practice the ’296 patent, then the marking requirement under § 287 would not apply. Under 35 U.S.C. § 286, “no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action.” This case was first filed on November 20, 2017. D.I. 1. Plaintiffs’ expert stated that “the Damages Period would begin on the date of first infringement, October 2015” D.I. 209-4, Ex. 48 at 14. However, in the parties’ proposed final jury instructions, UTBOR and TissueGen explain that “Boston Scientific may have beg[un] infringing prior to beginning commercial sale of the Synergy stents (i.e. during clinical development and trials).” D.I. 272 at 24 n.41. BSC fails to show that UTBOR and TissueGen anywhere disclaimed these earlier-in-time damages. Thus, the Court rejects BSC’s proposed deletion.

For the reasons above, the Court adopts-in-part and rejects-in-part the changes that the parties propose to the Court’s jury instruction on marking.

WHEREFORE, at Wilmington this 20th of January, 2023, **IT IS HEREBY ORDERED** that the Court adopts in full the attached jury instruction as the jury instruction on patent marking in this case.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE